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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,323	09/20/2005	Richard M. Simonson	GWK-101-US	5343

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EXAMINER	
JAGOE, DONNA A	
ART UNIT	PAPER NUMBER
1614	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/525,323	SIMONSON ET AL.	
	Examiner	Art Unit	
	Donna Jagoe	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments filed March 19, 2009 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-8 are pending in this application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richter et al. U.S. Patent No. 3,961,629, Shanbrom U.S. Patent No. 5,811,471, Mosbey et al. U.S. Patent No. 7,030,203 B2. and Drug Facts and Comparisons, 1994 (U).

Richter et al. teach an antimicrobial absorbent material and a process of making said material wherein antimicrobial agents such as hexachlorophene, chlortetracycline, neomycin and penicillin are added (column 8, lines 34-37) to the polyurethane sponge (column 3, lines 54-55) and the process of making said sponge wherein the sponge is soaked in the germicidal agent/water/surfactant/glycerin dispersion and while submerged in the bath the foam advances through compression rolls into impregnation bath which is contained in the tank. As foam expands, bath rushes into the foam pores to impregnate foam. The foam passes under infrared lamps whereby water is vaporized and removed from foam. The dry foam is then packaged (column 8, lines 38-61). Impervious backing is recited (column 10, lines 8-10).

Richter et al. differs in that it does not teach the specific antimicrobial dye.

Shanbrom teaches a germicidal absorptive dressing in a sponge-like matrix made of polyvinyl alcohol-acetal polymer combined with germicidal disinfectant dye,

such as gentian violet. The presence of bound disinfectant dye allows the sponge to inhibit bacterial growth in a number of different situations (see abstract). The disinfectant is dissolved in a solution of water and 1-2% glycerin (column 3, lines 45-48). Further motivation to employ glycerin comes from the teaching of Shanbrom that disinfectant dyes are quite soluble in glycerin, therefore treatment solutions containing 50% or more glycerin are very useful. The final wash solution can also advantageously contain a low percentage of glycerin because a trace of glycerin left in the PVA can help maintain softness and improve future water uptake when the material is dried (column 3, lines 42-47).

Richter et al. teach the medical sponge/pad made of polyurethane and the method of making a medical sponge/pad differing in the selected antimicrobial agent employed.

Shanbrom teaches antimicrobial dye employed in germicidal absorptive material, such as gentian violet. The antibacterial activities of these germicidal dyes are well known in the art and disclosed in Shanbrom. One of ordinary skill in the art could have substituted the gentian violet of Shanbrom for the antimicrobial agents, hexachlorophene, chlortetracycline, neomycin or penicillin of Richter et al. and the results of the substitution would have been predictable. It would have been prima facie obvious to substitute one antimicrobial for the other. Express suggestion to substitute one equivalent for another need not be present to render such substitution obvious.

Regarding the addition of 8 drops of 1% gentian violet to the water and glycerin, since the amount of water/glycerin is not disclosed one cannot ascertain a final concentration of gentian violet. It remains obvious over the prior art for the reasons

detailed supra. With regard to the process of instant claim 7 drawn to "bedsore sheeting", the intended use of the process of making the sponge must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. Since the sponges of the patents are capable of being used as a pad for bedsores, then it meets the claim. With regard to the limitations of instant claim 1, drawn to the concentration of gentian violet being between one and three percent, it would have been obvious to employ gentian violet in this range motivated by the teachings of Drug Facts and Comparisons who teaches that 1-2% are concentrations are known and available commercially.

With regard to the pressure sensitive adhesive (PSA) addressing the limitations of instant claim 7, Mosbey et al teach PSA adhere to skin in medical applications such as medical tapes and dressings (column 14, lines 25-42). It would have been obvious to employ the PSA of Mosbey et al. to adhere the polyurethane dressing/pad of Shanbrom and Richter et al. to the skin motivated by the teachings of Mosbey et al. that PSA are employed in medical tapes and dressings and as such would be expected to adhere as in the case of bedsore sheeting.

Thus the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Accordingly, for the above reasons, the claims are deemed properly rejected and none are allowed.

Response to Arguments

Applicant states that a key benefit of the applicants' pad is that the glycerin keeps the polyurethane soft while allowing exudate from wounds to be absorbed by the pad/sponge. In response, Shanbrom teaches that a trace of glycerin left in the PVA (sponge/pad) can help maintain softness and improve future water uptake when the material is dried (column 3, lines 42-47). The improvement of future water uptake would be inclusive of watery exudate from a wound. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the lack of "tattooing of the skin" in an ulcerative lesion) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant states that Richter et al. does not teach the antimicrobial dye. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Donna Jagoe /D. J./
Examiner
Art Unit 1614

July 21, 2009

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614